

FOR IMMEDIATE RELEASE
Monday, Oct. 18, 1999

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**STATEMENT BY DONNA E. SHALALA
Secretary of Health and Human Services
Regarding Issuance of OPTN Final Rule Amendments**

"Today my Department is issuing an amended regulation to carry out the shared responsibilities under the National Organ Transplant Act. The amended rule includes important changes that reflect the constructive input we received over the past year from the Congress, the Institute of Medicine and representatives of the transplant community. We appreciate the many suggestions we have received, and we look forward to continuing and improving our partnership with the transplant community in making our transplantation system as effective and fair as it can be.

"The Department has worked hard to fulfill the intent of Congress since the legislative moratorium was placed on our Final Rule. The Congress asked for three courses of action: a report by the Institute of Medicine to examine these issues closely; development of improved transplantation data; and renewed discussions between HHS and the various members of the transplant community to improve our understanding of the various points of view.

"Today, those three steps have been taken, and I believe all of us have learned significant lessons as a result of these extra efforts.

"The Institute of Medicine delivered a landmark study in July, using a breadth of data never before available to researchers, and performing enlightened analyses of that information. All of us concerned with transplantation policy are indebted to the IOM committee for its work.

"Likewise, the Department explored new avenues for providing useful, transplant center-specific information for patients, physicians and the entire transplant community. This work was provided to Congress this month, and has also been conveyed to the Scientific Registry of Transplant Recipients for appropriate further development.

"Finally, we have concluded a series of meetings with representatives from all sides of the transplant community. We conducted a dozen meetings with representatives of 11 different groups, and we listened to all concerns. In our final meeting, we invited all these groups to come together to discuss the rule.

"Today, the amendments to our Final Rule rely heavily on the findings of the IOM. They also reflect the concerns we have heard in our discussions with the transplant community.

"These amendments improve and refine the Final Rule. They make much clearer the separation of roles between the federal government and the transplant professionals who make the medical decisions. They add a significant new element, an independent advisory committee to assure that HHS has the best scientific counsel as it oversees the broad policies of the Organ Procurement and Transplantation Network, consistent with the law. They provide for appropriate representation by transplant physicians and surgeons, and by patient and donor representatives, in the leadership of the OPTN. They envision a more vigorous role for the OPTN in assuring that consistent medical criteria are used, so that we can be assured that organs are being allocated in the fairest and most medically effective manner. And they provide expanded flexibility for development of performance criteria, including modifications in keeping with the IOM's recommendations concerning the use of waiting time as a performance measure.

"As the Final Rule is put in place, we look forward to the establishment of policies by the OPTN that reflect the following core principles:

- Organs must be allocated according to uniform medical criteria, which are developed by the transplantation community. Likewise, the transplantation community should design fair and effective criteria by which the performance of the system can be measured.
- Organ sharing must take place over broad enough areas to ensure that organs can reach the patients who need them most, and for whom transplantation is most medically appropriate.
- There are appropriate and distinct roles to be played by both the federal government and the organ transplant community. In particular, HHS does not seek to interfere in the practice of medicine, but rather to assume proper responsibility, as specifically reaffirmed by the IOM, for ensuring that the transplantation system as a whole operates in the public interest.
- The best possible information must be made available to physicians and patients, both to help in medical decision-making, and to learn the most successful practices and deliver the highest quality care.

"These principles were reinforced by the findings of the IOM. They are simple and powerful goals that we can all share.

"During the past year, we have gained the important input of the IOM, we have developed some promising new analyses of transplant data, and we have gained greater clarity about our common purposes and how to reach them.

"Now it is time to move forward toward the goals we share: increased donation of organs, and best medical use of every organ that is donated. It is time to take the steps that can make our transplant system work better and save more lives. It is time to translate our words and our intentions into action that benefit patients."

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